NASA Procedural Requirements

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COMPLIANCE IS MANDATORY

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Request Notification of Change (NASA Only)

Subject: NASA Health and Medical Requirements for Human Space Exploration

Responsible Office: Office of the Chief Health & Medical Officer

Appendix D. Transition to Operations Review Process

D.1 The Transition to Operations Review Process (TORP) is designed to assess the effectiveness and operational readiness of human health-related research and technology products and deliverables. It provides a clear channel for human health and medical-related flight and ground research results, and technology development that can impact crew health and performance, for transition to tools available to support Agency human space flight programs.

D.2 The TORP review process will be conducted according to the process described below. It will be applied to newly proposed health and medical procedures, practices, processes (including, when deemed appropriate, "off-label" uses of medications, therapies, and technologies), countermeasures, or technologies resulting from NASA-sponsored research or technology development that are designed to maintain the health, performance, and/or support the medical care of space flight crews. The initial evaluation will be through JSC human space flight HMTA management structure before a recommendation is made to the CHMO for the final review.

D.2.1 The submitting organization presents a proposal for TORP review of a research or technology deliverable or product to the appropriate JSC configuration control board and/or the Aerospace Medicine Board (AMB); for subsequent consideration by the JSC Human System Risk Board (HSRB). The proposal will include the following documentation:

(1) A detailed description of the deliverable or product, its intended use or application, and a description of how the deliverable or product addresses a NASA-identified critical risk, medical, health or performance issue, or application.

(2) Data demonstrating the efficacy, effectiveness, or utility of the deliverable or product.

(3) Data demonstrating the operational validation of the deliverable or product.

(4) An implementation plan of how the product or deliverable is to be used or applied (e.g., protocol, dosing regime, scope of use).

(5) An analysis of the mission resources (e.g., crew time, volume, power, etc.) necessary to implement the product or deliverable.

(6) A summary of the developmental process and milestones the product or deliverable underwent.

D.2.2 Upon recommendation by the HSRB, the submitting organization provides a written request for TORP review of a research or technology deliverable or product to the JSC CMO. The JSC CMO recommends to the NASA CHMO that a panel be convened.

D.2.3 The submitting organization provides the documentation package described above and board recommendations to the NASA CHMO in advance of the TORP review.

D.2.4 Depending on the nature of the product or deliverable, at least one of the reviews below will be conducted to evaluate the operational readiness of the product or deliverable. The CHMO determines which type of review(s) should be conducted.

(1) Operational assessment - The developmental history and overall utility and effectiveness of the product or deliverable will be assessed by a panel of NASA internal experts with relevant technical and operational expertise for the product or deliverable.

(2) Scientific/technical review - The underlying scientific and/or technical basis and rationale, as well as operational utility and effectiveness, of the product or deliverable will be assessed by a panel of NASA internal and external experts with relevant scientific, technical, and operational expertise for the product or deliverable.

(3) Medical Policy Board review - The product or deliverable supporting documentation, and any results and recommendations from the other two reviews, will be reviewed by the Medical Policy Board for concurrence on recommended course of action.

D.2.5 The TORP panel(s) provides one of the following recommendations for consideration by the NASA CHMO:

- Approve: The CHMO will certify the product or deliverable for NASA medical practice.
- Approve with Revision/Recommendation: The CHMO will certify the product or deliverable as NASA medical practice, with revisions or recommendations to the implementation plan or scope of use, as indicated by the TORP review panel.
- Defer: A decision regarding the product or deliverable will be deferred until additional information can be supplied to the review panel. This may be a request for additional supporting documentation or for additional data collection and/or experimentation.
- Reject: The product or deliverable will not be certified as NASA medical practice.

D.2.6 The OCHMO will convey, in writing, the results of the TORP review to the submitting organization and to the JSC CMO.

D.2.7 Once approved, the product or deliverable will be available for use according to established NASA policy.

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